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 and Mallinckrodt plc

INTERNATIONAL UNION OF OPERATING	:	IN THE MONTGOMERY COUNTY
ENGINEERS LOCAL 542	:	COURT OF COMMON PLEAS

v.

MALLINCKRODT ARD, INC., formerly	:	
known as QUESTCOR	:	No. 2018-14059
PHARMACEUTICALS, INC.	:	

MALLINCKRODT PLC	:	
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EXPRESS SCRIPTS HOLDING COMPANY	:	
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EXPRESS SCRIPTS, INC.	:	
CURASCRIP, INC.	:	

CURASCRIP SD	:	
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ACCREDITO HEALTH GROUP, INC.	:	
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and

UNITED BIOSOURCE CORPORATION, now	:	
known as UNITED BIOSOURCE LLC., a	:	
wholly owned subsidiary of UNITED	:	
BIOSOURCE HOLDINGS, INC.	:	

REPLY IN SUPPORT OF PRELIMINARY OBJECTIONS OF DEFENDANTS
MALLINCKRODT ARD INC. AND MALLINCKRODT PLC

Defendants Mallinckrodt ARD Inc. and Mallinckrodt plc (collectively, “Mallinckrodt”) submit this Reply in Support of Preliminary Objections to Plaintiff International Union of Operating Engineers Local 542 (“Plaintiff”)’s Amended Complaint filed on August 27, 2018.

Plaintiff’s Opposition to Mallinckrodt’s Preliminary Objections and the corresponding Omnibus Memorandum of Law in Opposition to the Preliminary Objections of Defendants are full of misstatements regarding Mallinckrodt’s position along with strawman arguments and unsupported and incorrect musings on the status of the law. Indeed, much of Plaintiff’s opposition is rhetoric that simply tries to muddle the issues before the Court. Separately and together, they fail to provide any support for overruling Mallinckrodt’s Preliminary Objections to the Amended Complaint.

ARGUMENT

In considering the sufficiency of Plaintiff’s claims, “[t]he pleader’s conclusions or averments of law are not considered to be admitted as true by a demurrer.” *Allegheny Cty. v. Com.*, 507 Pa. 360, 372, 490 A.2d 402, 408 (Pa. 1985) (internal citations omitted). In light of this standard, Plaintiff’s Amended Complaint, with six state law claims against Mallinckrodt—Count I (Pennsylvania Unfair Trade Practices and Consumer Protection Law); Count II (Negligent Misrepresentation); Count III (Aiding and Abetting/Civil Conspiracy); Counts IV and V (Unjust Enrichment); and Count IX (Declaratory and Injunctive Relief)—cannot survive.

Plaintiff incorrectly argues that “Mallinckrodt’s Preliminary Objections are unchanged from its original Preliminary Objections.” Pl. Opp. 4. However, to the extent that Mallinckrodt has repeated certain arguments from its original objections, it did so because Plaintiff’s Amended Complaint changed the form but not the substance of the original complaint. Although Plaintiff claims it has “clarified” issues in its Amended Complaint, it has done nothing to fix the

problems. As such, the Amended Complaint is subject to the same objections, including a demurrer as to each count for failure to state a claim, as the initial complaint. Unlike in *Allegheny Inst. Taxpayers Coalition v. Allegheny Reg'l Asset Dist.*, relied on by Plaintiff, here the amendment has not “remove[d] all of which the defendant has complained.” 556 Pa. 102, 113 (1999). Consequently, the amended allegations do not provide viable causes of action under Pennsylvania law any more than did the initial allegations.

1. Plaintiff cannot recover for antitrust damages under Pennsylvania law.

Plaintiff's Amended Complaint, like the original complaint, alleges that Mallinckrodt engaged in behavior that improperly maintained and enhanced its monopoly power, thus enabling it to charge high prices for Acthar resulting in injury to Plaintiff. Specifically, Plaintiff alleges that:

- This case “seeks to challenge the lawfulness of Mallinckrodt’s exercise of monopoly power by taking actions to maintain and enhance that monopoly power.” Pl. Am. Compl. ¶ 4.
- Plaintiff “thus paid more for Acthar than it otherwise would have paid in the absence of . . . [the] conspiracy between Mallinckrodt and Express Scripts to maintain and enhance Mallinckrodt’s monopoly power, allowing it to charge exorbitant prices.” Pl. Am. Compl. ¶ 11.
- “The brunt of these monopoly prices was borne by self-funded payors, like IUOE Local 542.” Pl. Am. Compl. ¶ 154.
- “Mallinckrodt, by working with Express Scripts in maintaining and enhancing its monopoly, and its exercise of monopoly power through increasing prices over a decade, and engaging in other unlawful acts and practices, Mallinckrodt was able to extract

exorbitant revenue from IUOE Local 542 beyond what it could have received in the absence of such unlawful conduct.” Pl. Am. Compl. ¶ 218.

Plaintiff argues that because it removed certain antitrust “buzzwords” from the Amended Complaint it no longer seeks damages for violations of antitrust law. Yet, the Amended Complaint still contains over forty references to monopoly-related behavior. Removing *some* antitrust terms and adding awkward conclusory references to “deception” and “misrepresentation” does not alter the fact that Plaintiff is seeking damages solely for higher prices resulting from alleged anticompetitive behavior. However, Pennsylvania law does not allow for such damages. *See XF Enterprises, Inc. v. BASF Corp.*, 47 Pa. D. & C.4th 147, 150; *see also Stutzle v. Rhone-Poulenc S.A.*, No. 002768OCT.TERM2002, 2003 WL 22250424, at *2 (Pa. Com. Pl. Sept. 26, 2003) (“the Pennsylvania legislature and the courts have not created a cause of action for damages sustained as a result of the antitrust violations”). In short, in substance these remain antitrust claims, and Plaintiff cannot recover under any state law theory of recovery.

2. All claims are deficient as the allegations pled fail to satisfy the elements of the respective claims, and Mallinckrodt’s demurrer should be sustained.

With respect to its statutory claim under Pennsylvania’s Unfair Trade Practices and Consumer Protection Law (“UTCPL”), 73 Pa. Stat. § 201 *et seq.*, even if Plaintiff has standing to sue, the conduct alleged does not fall within the categories of proscribed conduct. Moreover, even if it did, Plaintiff fails to allege the necessary reliance and causation. In response, Plaintiff states that it “alleges both reliance and causation, as required and where required.” Pl. Opp. ¶ 22; Pl. Omnibus Br. 13. Plaintiff then points to the allegations at Paragraphs 10–11, 180–182, 186–187, 189–191, and 230, and while those may refer to reliance in conclusory form, Plaintiff does

not allege any facts that it purchased Acthar due to any misrepresentations made by Mallinckrodt. When such facts are lacking, courts typically dismiss UTPCPL claims against manufacturers. *See, e.g., Ironworkers Local Union 68 v. AstraZeneca Pharm., LP*, 634 F.3d 1352, 1363 (11th Cir. 2011) (affirming dismissal of labor union's UTPCPL claim premised on alleged misrepresentations).

On a related point, Plaintiff frequently relies on *Commonwealth v. TAP Pharmaceutical Products* in support of its UTPCPL claims. While both cases involve the concept of average wholesale prices (or "AWP"), that case is factually distinguishable from the current matter. In *TAP*, the plaintiffs alleged that drug manufacturers "knowingly inflated [a] self-reported AWP for inclusion in a pharmaceutical publication upon which the Commonwealth relied." 885 A.2d 1127, 1132 (Pa. Commw. 2005). While Plaintiff has also alleged inflated prices here, critically it has not alleged any false reporting to third parties. Here, Plaintiff only takes issue with the high prices (and related AWP) for Acthar which it claims stem from an alleged exclusive distribution arrangement for Acthar between Mallinckrodt and Express Scripts and the purchase of a potentially competitive drug, Synacthen, by Mallinckrodt's predecessor, Questcor. *See Am. Compl. ¶ 5*.¹

With respect to its negligent misrepresentation claim, Plaintiff quickly discounts the economic loss doctrine with little analysis. However, unless Plaintiff can show that an exception applies, its claim for purely economic losses is barred under this doctrine. And, the sole narrow exception derived from Section 552 of the Restatement of Torts is relevant only where the "defendant is in the business of supplying information for the guidance of others and the

¹ Plaintiff boasts that "counsel for Local 542 successfully prosecuted the UTPCPL claims of self-funded Commonwealth entities who reimbursed the prescription drugs of their beneficiaries all the way through trial." Pl. Omnibus Br. 14. However, Plaintiff omits the fact that a favorable trial outcome for the Commonwealth was subsequently vacated. *See Com. v. TAP Pharm. Prod., Inc.*, 626 Pa. 1, 94 A.3d 350 (2014).

information provider must have a pecuniary interest in the transaction.” *Excavation Techs., Inc. v. Columbia Gas Co. of Pennsylvania*, 2007 PA Super 327, ¶ 11, 936 A.2d 111, 115–16 (2007), *aff’d*, 604 Pa. 50, 985 A.2d 840 (2009) (“The Supreme Court made clear in its rationale that application of § 552 liability for economic loss was limited to design professionals, such as architects[.]”).

In seeking to invoke this exception, Plaintiff’s reliance on *Commonwealth v. TAP Pharmaceutical Products*, 36 A.3d 1197, 1277 (Pa. Commw. Ct. 2011), vacated, 626 Pa. 1 (2014), is again misplaced. There, the Court specifically found the “facts of the present case [fell] within the parameters of Section 552 of the Restatement.” *Id.* But, the exception does not apply here. Courts have more recently held that merely providing information ancillary to the sale of prescription drugs does not mean one is in the business of providing information. *See Elliott-Lewis Corp. v. Skanska USA Bldg., Inc.*, No. 14-3865, 2015 WL 4545362, at *5 (E.D. Pa. July 28, 2015) (“The sale of a product is fundamentally different than the sale of information, even if the seller provides information about the product to consummate the sale.”); *see also Whitaker v. Herr Foods, Inc.*, 198 F. Supp. 3d 476 (E.D. Pa. 2016) (“Defendant manufactures and labels snack foods . . . The label, of course, supplies information to potential consumers; but the representations on a product’s label made by a manufacturer materially differ from the professional representations made by an accountant, lawyer, or architect for pecuniary gain[.]”). Consequently, the economic loss doctrine is a bar to Plaintiff’s negligent misrepresentation claim because Mallinckrodt is not in the business of providing information.

With respect to its unjust enrichment claim, Plaintiff has not alleged any unjust benefit to Mallinckrodt vis-à-vis its purchase of Acthar from Express Scripts. Under Pennsylvania law, “[t]he doctrine does not apply simply because the defendant may have benefited as a result of the

actions of the plaintiff.” *Wiernik v. PHH U.S. Mortg. Corp.*, 736 A.2d 616, 622 (Pa. Super. Ct. 1999) (internal citation omitted) (finding “any alleged benefit received by appellees did not constitute unjust enrichment”). On a related point, other than some conclusory remarks, Plaintiff provides no opposition to the case law which clearly provides that an indirect purchaser (like Plaintiff is to Mallinckrodt) cannot recover under an unjust enrichment theory. *See Stutzle v. Rhone-Poulenc S.A.*, No. 002768OCT.TERM2002, 2003 WL 22250424 (Pa. Com. Phila. Cty. 2003).

Furthermore, as in *Stutzle*, the Amended Complaint here makes clear that the unlawful behavior which supposedly led to Mallinckrodt’s unjust enrichment was an alleged antitrust violation, namely “maintaining and enhancing its monopoly, and its exercise of monopoly power through increasing prices over a decade.” Pl. Am. Compl. ¶ 218. The Court in *Stutzle* ruled that “[s]ince the Pennsylvania legislature and the courts have not created a cause of action for damages sustained as a result of an antitrust violation,” plaintiffs had failed to establish how any benefits to defendant were unjust. 2003 WL 22250424 at *2; *see also In re Solodyn (Minocycline Hydrochloride) Antitrust Litig.*, No. CV 14-MD-02503-DJC, 2015 WL 5458570, at *20 (D. Mass. Sept. 16, 2015) (dismissing unjust enrichment claim under Pennsylvania law based on alleged antitrust injury).

With respect to its aiding and abetting claim, Mallinckrodt does not dispute that the law provides a cause of action where a party gives substantial assistance to the wrongful conduct of another. Here, however, as explained in Mallinckrodt’s initial brief, Plaintiff has not alleged underlying tortious conduct or the existence of a duty owed to Plaintiff on which to support a claim for aiding and abetting. And, Plaintiff’s conclusory statements of an alleged “conspiracy” lack the specificity required to survive the demurrer to the extent it brings a related cause of

action for civil conspiracy. *See Armstrong v. Allied Dev., Inc.* No. 06-02298, 2010 WL 5805708 (Pa. Com. Pl. Lycoming Cty. 2010), *aff'd sub nom, Armstrong v. Allied Dev.*, 29 A.3d 822 (Pa. Super. Ct. 2011).

Finally, Plaintiff's sole authority in support of its declaratory and injunctive relief claim, *Commonwealth v. TAP Pharmaceutical Products*, is again inapposite here. 36 A.3d 1112 (Pa. Cmwlth. 2011), vacated, 626 Pa. 1 (2014). As discussed above, that case involved claims that the Commonwealth brought and not a private person or entity like Plaintiff in this case. Accordingly, a different standard applied for an injunction: "The plain language of this section authorizes the Attorney General to seek an injunction in the name of the Commonwealth where he has reason to believe (1) a 'person' is violating the CPL; and, (2) such proceedings are in the public interest." *Id.* at 1157. Plaintiff's desired relief "for the potential future harm of additional beneficiaries who may be prescribed Acthar" is simply too speculative. *See* Pl. Omnibus Br. 23. This private party Plaintiff has failed to make the necessary showing of future harm. *See Abrams v. Toyota Motor Credit Corp.*, 2001 WL 1807357 (Pa. Ct. Comm. Pl. 2001).

3. The Amended Complaint also fails to attach a contract at issue, includes scandalous and impertinent matter, and lacks specificity in certain areas.

With respect to form, the Amended Complaint still fails to comply with Pennsylvania Rule of Civil Procedure 1019(i). To the extent Plaintiff seeks to hold Mallinckrodt liable for actions of Express Scripts, the underlying contract between Express Scripts and Plaintiff is relevant to this case and is required to be attached to Plaintiff's pleading. Moreover, that contract forms the basis of numerous allegations incorporated by reference throughout Plaintiff's causes of action.

Additionally, Plaintiff chose not to remove the scandalous and impertinent matter from its complaint while drafting the amended version, and Paragraph 5, 40, 41, 114-115, 143-147, and 152-154 of the Amended Complaint merit striking under Pennsylvania Rule of Civil Procedure 1028(a)(2). Those paragraphs include prejudicial language and inappropriate references to the earlier FTC and Retrophin litigations. On this issue, Plaintiff inaccurately represents that “Mallinckrodt provides this Court with no case law as to what constitutes ‘scandalous or impertinent matter’ rising to the level that warrants an averment being stricken from a complaint[.]” Pl. Opp. ¶ 59. In fact, Mallinckrodt cited three cases on that point in its initial brief which provide examples of language that has been stricken in the past. *See Berardi v. Prestige Homesites Inc.*, 80 Pa. D. & C.4th 215, 216 (Pa. Com. Pl. Monroe Cty. 2006) (striking words “theft” and “criminal nature” deemed “immaterial and inappropriate to the proof necessary to the cause of action”); *see also Common Cause/Pennsylvania*, 710 A.2d 108 (striking “editorialized history” of events as immaterial and scandalous); *JHE, Inc. v. Se. Pennsylvania Transp. Auth.*, No. 1790 NOV.TERM 2001, 2002 WL 1018941, at *10 (Pa. Com. Pl. Phila. Cty. May 17, 2002) (striking “extraneous comments” regarding “emotions and intentions” which prejudiced defendant by portraying it as “unscrupulous”). Taken together, these cases make clear that the allegations of the sort at issue here are inappropriate in a pleading.

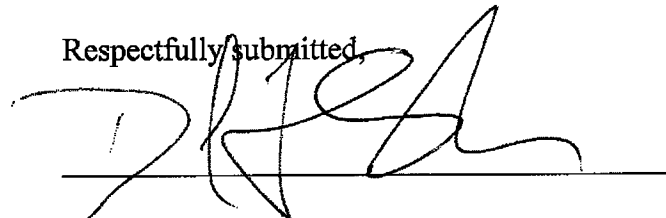
In opposition, Plaintiff contends that Mallinckrodt failed to ask for the attached FTC and Retrophin complaints *themselves* to be struck. This is incorrect. The paragraphs which purport to attach those extraneous complaints as exhibits to the Amended Complaint are included above and precisely targeted by Mallinckrodt’s preliminary objections. Plaintiff also claims that “[t]he facts of these two complaints, incorporated by reference into Local 542’s Amended Complaint,

will remain, regardless of what the court chooses to do with Mallinckrodt's Preliminary Objection." Pl. Opp. ¶60. Not true. It is clear that Plaintiff is trying to garner an improper advantage by casting Mallinckrodt in a negative light and relying on "facts" outside of the pleadings. But, a party cannot rely on "facts" outside of those pled in its complaint. *Williams v. Nationwide Mutual Ins. Co.*, 750 A.2d 881 (Pa.Super.2000) (citation omitted) ("Preliminary objections in the nature of a demurrer require the court to resolve the issues solely on the basis of the pleadings; no testimony or other evidence outside of the complaint may be considered to dispose of the legal issues presented by the demurrer."). The Court should strike the paragraphs at issue.

Finally, the Amended Complaint still lacks detail and substance where it matters. The fact that there is a large quantity of substance-free allegations does not prove otherwise. Plaintiff fails to meet its pleading burden under a fact pleading standard for those claims which require enhanced particularity. *See* Pa. R. Civ. P. 1019(b).

WHEREFORE, Mallinckrodt respectfully requests that this Honorable Court sustain these Preliminary Objections and enter the Proposed Order, as previously submitted, dismissing Plaintiff's Amended Complaint with prejudice as to Mallinckrodt.

Respectfully submitted,



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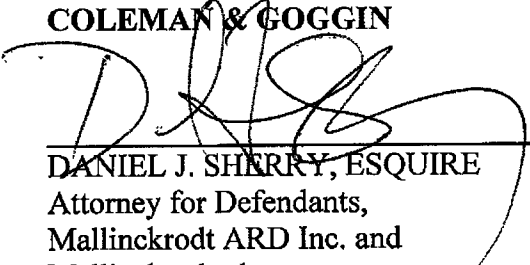
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BIOSOURCE HOLDINGS, INC. :**CERTIFICATE OF COMPLIANCE**I certify that this filing complies with the provisions of the Public Access Policy of the
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BIOSOURCE HOLDINGS, INC. :**CERTIFICATE OF SERVICE**Daniel J. Sherry, Esquire hereby certifies that a true and correct copy of the foregoing
Reply in Support of Preliminary Objections of Defendants Mallinckrodt ARD Inc. and

Mallinckrodt PLC to Plaintiff's Amended Complaint was electronically filed and forwarded to the following via email and/or United States First Class Mail, postage prepaid, on October 19, 2018:

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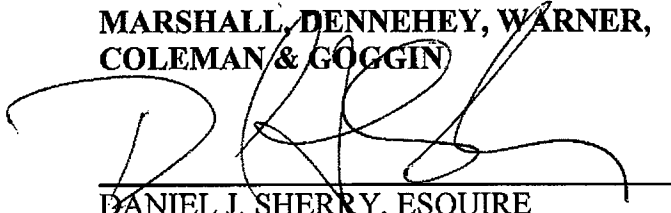
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